K080406

CyDen

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FDA Center for Devices and Radiological Health
Document Mail Center, HFZ-401
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

FEB 14 2008

Received

8th February 2008

510(k) Notification

The document in intended to provide the necessary information required by the FDA for the pre-market 510(k) approval for the **iPulse i400 System**.

510(k) Administration Information

Submitter:	Cyden Limited Technium, Kings Road, The Docks Swansea SA1 8PH, Wales, UK
Official Contact:	Dr Mike Kiernan Consultant
Telephone: **Fax:** **Email:**	UK +44 1792 485682 UK +44 1792 485524 mikekiernan@hotmail.com
SubmissionType:	SPECIAL 510(k)
Device Type:	Intense Pulsed Light Source
Classification Regulation:	The iPulse System is a Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology and therefore is classified under **21 CFR 878.4810**
Class:	[redacted]
Panel:	[redacted] General and Plastic Surgery
Product Code:	GEX - Laser Powered Surgical Instruments (and Accessories)
Submission Basis:	Modification to Existing Device

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In accordance with the guidelines, the principle factors about the design and use of the device are tabulated in Table 1.

Table 1: Design and Use of the Device		
	YES	**NO**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	YES	
Is the device intened for over-the-counter use (21 CFR 807 Subpart C)?		NO
Does the device contain components derived from a tissue or other biological source?		NO
Is the device provided sterile?		NO
Is the device intended for single use?		NO
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?	YES	
Does the submission include clinical information?		NO
Is the device implanted?		NO

Please call me on the above number if you have any queries or comments.

Dr Mike Kiernan
Consultant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CyDen Limited
% Dr. Mike Kiernan
Technium, Kings Road
The Docks
Swansea, SA1 8PH
Wales, UK

MAR 10 2008

Re: K080406
Trade/Device Name: IPL iPulse i400 Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 3, 2008
Received: March 5, 2008

Dear Dr. Kiernan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080406

Indications for Use Statement

510(k) Number (if known): Unknown

Device Name: IPL iPulse i400 System

Indications For Use:

The iPulse System is a laser surgical instrument for use in General and Plastic Surgery and Dermatology and specifically for long term stable, or permanent, hair reduction.

In addition, the iPulse System is indicated for the treatment of benign cutaneous vascular lesions and the treatment of benign pigmented lesions.

The iPulse System is indicated for the treatment of mild to moderate inflammatory Acne Vulgaris.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080406